

Section Numbe	Title	Why Important	Simple Case	Complex Case
2.2.1	Title, Version, and Approval/ Sign-off	To meet the requirements of clause 7.6.3 of the Standards for an approved QAPP prior to initiating work	Single page with title and required signatures	Revisions history tracking all changes made to the QAPP over time
2.2.2	Document Format and Table of Contents	To make it easy for the project team and reviewers to find the information they need	Table of contents and page numbers	Document control format
2.2.3	Distribution List	To be sure that everyone who needs it has access to, and awareness of, the latest version of the QAPP	Included on the title page or in the project organization section	A separate section with contact information and indication of under what conditions each individual needs to be made aware of revisions to the QAPP
2.2.4	Project Organization and Schedule	To ensure all key project personnel are aware of their responsibilities and the timeframe for completion	Names of key project personnel and period of performance for project	Organizational chart of all key project roles with names and Gantt or similar tracking chart of schedule
2.2.5	Project Background, Overview, and	To provide sufficient information as a foundation for the project goals and to clarify the expected uses of the data	General overview and statement of how data and models will be used in this project	Detailed project history, references to other background documentation, regulatory basis for data use
2.2.6	Data/Project Quality Objectives and Measurement Performance Criteria	To ensure that the data or models collected or used in the project are of sufficient quality to support project decisions	Project goals, data required to meet those goals, statement of what criteria the data must meet to be acceptable for project use	7-step DQOs, MQOs for all DQIs, statement of tolerable error ranges for project decisions
2.2.7	Special Training Requirements and Certification	To be sure that the project has qualified personnel to perform all necessary functions	List of specialized training required in the project	Matrix of special training needs, personnel who are qualified, and timeframe of qualifications
2.2.8	Documentation and Records Requirements	To document project process, outcomes, and supporting quality information, to meet clauses 7.6.5 and 7.6.6 of the Standards	Statement declaring where project documentation will be stored, including, but not limited to: QAPP, data packages, assessment records, interim and final reports	Detailed documentation and storage requirements per regulation or contractual obligation. These may be indicated in the project schedule as well.
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2.3.1	Sample Collection Procedure, Experimental Design, and	To define the way the data will be collected and state whether it is a probability- based or judgmental design	Define population of interest, sample design and rationale for that design, number/time/location and types of samples to be collected	As appropriate, discuss multistage sampling, randomization procedures, stratification rationale, or any details that support the selection of samples
2.3.2	Sampling Procedures and Requirements	To ensure that appropriate sampling methods are selected to meet the project needs and produce data of sufficient quality for project decision-making	Include or reference SOPs for sample collection, on- site preservation, and cleaning and decontamination of sampling equipment	Include media-specific sample collection procedures, safety issues involved in sample collection, sample container descriptions, etc.
2.3.3	Sample Custody Procedures, and Documentation	To ensure sample authenticity and to avoid sample loss	Describe sample documentation and handling procedures and include a sample chain-of-custody form	List US DOT regulations and how they will be met, explain sample numbering schema, define procedures for introducing PE samples
2.3.4	Analytical Methods Requirements and task Descriptions	To be sure appropriate measurement methods exist to achieve project quality objectives	Describe measurement techniques, such as counting, visual discrimination, or analytical methods	Details of analytes to be measured, analytical method, SOPs, data-package requirements, analytical laboratory contact information, and MQOs
2.3.5	Quality Control Requirements	To provide confidence that the project data are of suitable quality to be used for their intended	Number and types of QC samples to address sources of measurement error	Table of sources of potential measurement error and the corresponding QC samples that will be used to address those
2.3.6	Instrument/ Equipment Testing Calibration and Maintenance Requirements, Supplies and Consumables	To avoid poor instrument performance that could impact project data quality	Document roles and responsibilities and procedures for sample collection and measurement instrument inspection, calibration, and maintenance	Include instrument measurement uncertainty, traceability of calibration equipment, and project- specific schedule for inspection, calibration, and maintenance

2.3.7	Data Management Requirements	To ensure data integrity	Describe data handling from generation, to use, to final storage; include copies of data entry forms, reports and description of databases; specify any special requirements for data such as CBI or hardware/software	Include SOPs for data management, specify project personnel's roles and responsibilities regarding data management, describe how metadata will be gathered and stored with project data
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2.4.1	Technical Systems Assessments	To determine if the field sampling team, laboratory, or analysts have sufficient technical capabilities to generate data of appropriate quality for project use	If project-specific needs are minimal, noting accreditation to an appropriate technical system standard may be sufficient ; note that if any project- specific needs are more stringent than the standards, then project-specific assessments should be conducted	Describe plans for assessments of field sampling, on-site and off- site laboratory analyses
2.4.2	Performance Audits of Measurement and	To directly test that the measurement performance is adequate for project purposes	Document plans and acceptance criteria for split samples and PE samples, if	Specify schedule, analyte selection, traceability, spiking levels, and sample types (matrix, direct, single- blind, or double-blind), and include the sources and estimated costs for these samples
2.4.3	Surveillance of Operations	To verify that project activities are conducted as planned	State when surveillance will occur (under what conditions or by set timeframe), how it will be conducted, how feedback will be provided and incorporated, and if surveillance leads to a temporary or permanent work stoppage, address how that will be handled	Provide details of the triggering events for surveillance assessments, an SOP for their conduct, a list of who will be notified of any non-conformances observed during the assessments, and how the surveillance assessments
2.4.4	Audits of Data Quality	To be sure that the QC data are used to support data quality, and to determine if the data are replicable	Define the schedule (based on timeframe or triggering events) and scope for audits of data quality	Provide an SOP for conducting audits of data quality
2.4.5	Interim Assessments of Data Quality	To be sure data collection is proceeding according to plan	Include statement encouraging project team members to alert management if they sense anything isn't going quite right	Indicate points during the project timeline at which interim assessments of data quality will be conducted; state who will be responsible for their conduct and how they will be documented
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2.4.6	Qualitative and Quantitative Comparisons to Acceptance Criteria	To determine if the project quality objectives are met	State how comparisons to qualitative and quantitative MQOs will be evaluated; describe other criteria (e.g., publication in a peer- reviewed journal) that might be important for the project	Set specific comparison methodology for each DQI, such that there will be a definitive —pass/fail for each; describe contingencies in case of —fail
2.4.7	Evaluation of Unconventional Measurements	To be sure that any unusual laboratory methods are fully documented and understood	If no unconventional measurement methods will be/were used, just state that here	Describe the reason for using unconventional measurement methods, provide SOPs for their implementation and how efficacy will be assessed
2.4.8	Evaluation of Unconventional Monitoring Projects	To be sure that any unusual sample collection methods are fully documented and understood	If no unconventional sample collection methods will be/were used, just state that here	Describe the reason for using unconventional sample collection methods, provide SOPs for their implementation and how efficacy will be assessed
2.5.1	Data Verification and Validation Targets and Methods	To determine if data have met the project quality objectives	Provide a standard data verification and validation method or procedure that has been reviewed to ensure it meets project needs	Develop project-specific verification and validation schema that incorporate QC data and metadata
2.5.2	Quantitative and Qualitative Evaluations of Usability	To ensure that project decisions are supported by data of sufficient quality for project needs	State who will be part of the evaluation of data usability, how it will be conducted and documented	Define contingencies for any issues that may be identified during the evaluation of data usability
2.5.3	Potential Limitations on Data Interpretation	To ensure that the data are not stretched beyond their appropriate use	Describe what actions will be taken if project data are deemed unusable for their intended project purpose	Describe how any limitations will be documented and stored in the project metadata
2.5.4	Reconciliation with Project Requirements	To determine if the project requirements have been met	Clearly state how the data verification, validation, and usability results will be used to determine if the project requirements have been met; describe how the five steps of the DQA process will be conducted	State specific exceptions to statistical significance that will be overturned in favor of —practical significance! should they occur; define the steps to be taken for contingencies if the data do not support requirements
2.5.5	Reports to Management	To document project outcomes	Define schedule and content for reports to management	Provide report templates